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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/708,974 | 11/08/2000 | Philip A. Beachy | JHUC-P03-010 | 3945 |

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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,974

Applicant(s)

BEACHY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8, 11-17, 20, 22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-8, 11-17, 20, 22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 & 18. 6) ☐ Other:

Nonfinal Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Applicant's election with traverse of Group II and the species of cyclopamine in Paper No. 19 is acknowledged. The traversal is on the ground(s) that the steroidal alkaloids of Groups I and III-VIII have similar structures to jervine and cyclopamine and that examination of all Groups would not post significant additional burden to the examiner. This is not found persuasive because the structures of the various Groups are not similar as stated by applicant. For example, the compounds of jervine and cyclopamine do not have a cyclopentanohydrophenanthrene (steroidal) ring system because the C and D rings are not 6 and 5, respectively whereas tomatidine (see figure 1 of the present application) contains said ring system. Thus, a search of these compounds would require more than one search strategy.

The requirement is still deemed proper and is therefore made **FINAL**.

3. Based on applicant's election of Group II, claim 4 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 3, 5-8, 11-17, 20, 22 and 24-26 will be examined to the extent they read on compounds having the basic chemical structure of cyclopamine or jervine.

Claim Objections

4. The objection of claims 11-17 under 37 CFR 1.75(c) as being in improper form is withdrawn.

Double Patenting

5. The provisionally rejection of claims 1, 18 and 19 under the judicially created doctrine of double patenting over claims of copending Application No. 09/090,622 is made moot by the cancellation of the instant claims.

6. The provisionally rejection of claims 3, 5-8 and 20 under the judicially created doctrine of double patenting over claims of copending Application No. 09/090,622 is withdrawn.

7. The rejection of claims 1, 18 and 19 under the judicially created doctrine of double patenting over claims of US Patent No. 6,288,048 is made moot by the cancellation of the instant claims.

8. The rejection of claims 3, 5-8 and 20 under the judicially created doctrine of double patenting over claims of US Patent No. 6,288,048 is withdrawn.

9. Claims 3, 5-8, 11-17, 20, 22 and 24-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

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over claims 1, 15-17, 20, 21, 27, 28 and 36 of copending Application No. 09/708,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to inhibition of unwanted activation of hedgehog pathway, such as hair growth or spermatogenesis, utilizing compounds having the basic chemical structure of cyclopamine or jervine. The instant application differs from copending Application No. 09/708,964 by specifically reciting ~~the~~ inhibiting unwanted hair growth or inhibiting spermatogenesis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

- 10. The rejection of claims 1, 18 and 19 under 35 USC 112, first paragraph, scope of enablement, is made moot by the cancellation of the instant claims.**
- 11. The rejection of claim 20 under 35 USC 112, first paragraph, scope of enablement, is withdrawn.**
- 12. The rejection of claim 3 under 35 USC 112, first paragraph, as containing subject matter not described in the specification in a way to reasonable convey to the skilled artisan that applicant had possession of the claimed invention is withdrawn.**

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13. The rejection of claims 18 and 19 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.

14. The rejection of claims 3, 7 and 18-20 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.

N **15. The rejection of claims 5, 6 and 8 under 35 USC 112, second paragraph is maintained and claim 11 is rejected under 35 USC 112, second paragraph.**

Claims 5, 6 and 8 are indefinite because of the recitation that R₃ and R₅ can be =O or =S. It is noted that each of the carbon atom at C-10 and C-13 has only one free bond.

Claim 11 recites the phrase "and their derivatives". The present specification lacks description of what is encompassed by the phrase. Thus, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention.

For these reasons and those given in previous Office Actions, the rejection of claims 5, 6 and 8 under 35 USC 112, second paragraph is maintained and claim 11 is rejected under 35 USC 112, second paragraph.

Claim Rejections - 35 USC § 102

16. The rejection of claim 19 under 35 USC 102(b) over Gerashchenko et al. is made moot by the cancellation of the instant claim.

17. The rejection of claims 1, 3, 5-8, 18 and 20 under 35 USC 102(b) over Gerashchenko et al. is withdrawn.

18. The rejection of claims 1, 3, 5-8 and 18 under 35 USC 102(b) over Beachy et al. ('091) is withdrawn.

19. The rejection of claims 1, 3, 5-8 and 18 under 35 USC 102(b) over Beachy et al. ('048) is withdrawn.

20. Claims ¹⁰³24, ~~25~~ and ^m26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerashchenko et al.

Gerashchenko et al. teach a composition comprising jervine and its anti-inflammatory activity (see the entire article, especially page 2, paragraph 4). The composition and process of making said composition taught by the reference are encompassed by the instant claims.

21. Claims ¹⁰³24, ~~25~~ and ^m26 are rejected under 35 U.S.C. 102(b) as being anticipated by Omnell et al.

Omnell et al. teach an aqueous suspension comprising jervine and its teratogenic responses in mice (see the entire article, especially page 107, 2nd col., lines 4-6). The composition and process of making said composition taught by the reference is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

22. The rejection of claim 18 under 35 USC 103(a) over Gerashchenko et al. is made moot by the cancellation of the instant claim.
23. The rejection of claim 19 under 35 USC 103(a) over Beachy et al. ('091) is made moot by the cancellation of the instant claim.
24. The rejection of claim 19 under 35 USC 103(a) over Beachy et al. ('048) is made moot by the cancellation of the instant claim.
25. Claim ~~25~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerashchenko et al. or Omnell et al.

Each of Gerashchenko et al. and Omnell et al. teach a composition comprising jervine (see the entire article, **Gerashchenko et al.**, especially page 2, paragraph 4 and **Omnell et al.**, especially page 107, 2nd col., lines 4-6).

The instant claim differs from the references by reciting a topical formulation. However, formulation of various pharmaceutical preparation is within the level of skill of the skilled artisan in the pharmaceutical and, thus, the claimed invention is prima facie obvious. In addition, it is noted that aqueous suspensions/solutions can be utilized as topical preparation. The motivation to make different preparations is based on the desire to obtain a form that is convenient for administration.


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Telephone Inquiry

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
December 19, 2002